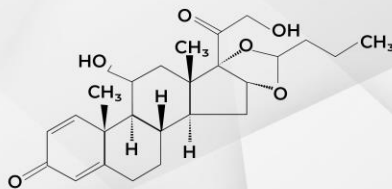


BUDESONIDE



PRODUCT IN FOCUS



Budesonide

INTRODUCTION

Budesonide is in a class of medications called corticosteroids. It works by decreasing inflammation (swelling) in the digestive tract of people who have Crohn's disease or ulcerative colitis. or in the kidney of people with nephropathy.

MANUFACTURE

It is manufactured by the reaction of 16 α -hydroxyprednisolone (11 β ,16 α ,17 α ,21-tetrahydroxypregna-1,4-diene-3,20-dione) with butyraldehyde in dioxane, using perchloric acid as catalyst.

APPLICATIONS

It is used for the treatment of:

- ✔ Asthma
- ✔ Inflammatory bowel disease
- ✔ Allergic rhinitis
- ✔ Eosinophilic esophagitis
- ✔ Berger's disease

Synonym

16,17-Butylidenebis(oxy)-11,21-dihydroxypregna-1,4-diene-3,20-dione

CAS no.

51333-22-3

EINECS no.

257-161-7

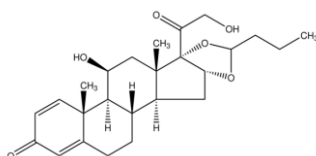
Molecular formula

C₂₅H₃₄O₆

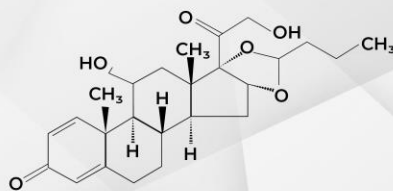
Molecular weight

430.5 g/mol

Structure



BUDESONIDE



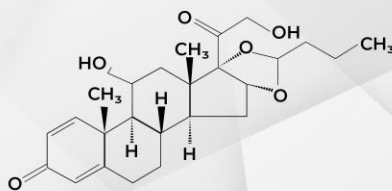
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SPECIFICATIONS... (EP)

Test	Unit	Specification
Appearance	-	White or almost white, crystalline powder.
Solubility	-	Practically insoluble in water, Freely soluble in methylene chloride, sparingly soluble in alcohol (96%).
Identification		
A) By IR Absorption	-	The IR spectrum of the sample should be concordant with that of a similar preparation of Budesonide standard.
B) By TLC	-	The principal spot of the test chromatogram should correspond to the principal spot of reference solution (a) at 254nm and 365nm.
C) By Chemical	-	The colour should fade and a clear solution remains.
D) By Chemical	-	The solution should turn blue.
Loss on drying	%	Not more than 0.5
Epimer A (Second Peak)	%	40.0 to 51.0
Related Substances (By HPLC)		
Impurity A	%	Not more than 0.2
Impurity D	%	Not more than 0.2
Impurity K	%	Not more than 0.2
Impurity L	%	Not more than 0.2
Unspecified impurities	%	Not more than 0.10
Total impurities	%	Not more than 0.5

BUDESONIDE



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SPECIFICATIONS... (EP)

...continued

Test	Unit	Specification
Assay (By HPLC) (on dried substance)	% w/w	97.5 to 102.0
Residual Solvents		
Methanol	ppm	Not more than 1000
Dichloro Methane	ppm	Not more than 600
n-butyraldehyde	ppm	Not more than 150
Benzene	ppm	Not more than 2
Dimethyl formamide	ppm	Not more than 880

PACKING

Fiber/HDPE drum.

STORAGE

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

CERTIFICATION

WHO-GMP, Written Confirmation for EU and CEP.

No matter the quantity you need, our exceptional quality and service will make ExSyn your supplier of choice! If you need any additional information or SDS, please contact us.