ASEAN Reference Substance (ARS)

ASEAN TECHNICAL COOPERATION IN PHARMACEUTICALS
supported by **Japan Pharmaceutical Manufacturers Association**

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Certificate of Analysis **PREDNISOLONE** **Control No. M 206011**

Description	:	A white, crystalline powder.
Infrared absorption	:	Concordant with the reference spectrum of Prednisolone USPRS.
Related substances	:	(HPLC method)
Any individual impurity	:	Less than 1.0%, and only one peak greater than 0.5%
Total impurities	:	Less than 2.0%
Loss on drying	:	0.29%
Assay	:	99.65% of $C_{21}H_{28}O_5$, calculated on the dried basis, determined by HPLC method, compared with USPRS.
Intended use	:	For HPLC assay and identification.
Direction for use	:	Dry at 105°C for 3 hours before use.
Storage	:	Keep container tightly closed and protected from light, preferably at the temperature about 5°C.

Date of Adoption	: 31 May 2006
Retested Date	: 1 June 2009, 21 May 2013, 31 May 2018
Next Retest Date	: 31 May 2021